MAY - 2 2001

510 (K) SUMMARY

Date of Summary: March 1, 2001

Product Name:

SURE CHECK Ovulation Predictor

Sponsor's Name:

Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763

Manufactured by:

Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763

Correspondent:

MDC Associates
Fran White
Regulatory Consultant (Director Regulatory Affairs Chembio Diagnostic Systems, Inc.)
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Devices:

Product: One Step Ovulation Predictor
Manufactured by: Self care, Inc. (Inverness)

PRODUCT DESCRIPTION:
The Ovulation Predictor is a midstream test used for the qualitative measurement of LH and the detection of Luteinizing Hormone (LH) surge in a woman's urine as an aid in reliably predicting ovulation. The ovulation predictor test is intended for use outside the body (*in vitro* diagnostic use) by women at home. The SURE CHECK Ovulation Predictor is an over-the-counter (OTC) device that will be sold under the SURE CHECK brand and various private labels.

INTENDED USE:

The SURE CHECK Ovulation Predictor test is a qualitative, one-step, midstream assay for the detection of human Luteinizing Hormone (LH) in urine as an aid in conception by reliably predicting ovulation. The SURE CHECK Ovulation Predictor test is intended for use by the lay consumer.

SUMMARY OF TECHNOLOGY:

The SURE CHECK Ovulation Predictor test employs a unique combination of monoclonal-dye conjugate (colloidal gold) and polyclonal-solid phase antibodies to selectively identify human Luteinizing Hormone (LH) in urine. As the urine flows through the absorbent portion of the device, the antibody-dye conjugate binds to the LH forming an antibody-antigen complex. This complex binds to the anti-LH antibody in the positive test zone and produces a pink-rose color band that is equal to or greater than that of the control band when the LH concentration is equal to or greater than 30 mIU/ml. In the absence of LH, there is no test line or a lighter test line than in the control zone. Unbound conjugate binds to the reagents in the control zone, producing a pink-rose color band, demonstrating that the reagents are functioning correctly.

PERFORMANCE DATA:

A clinical trial was done to compare the performance of the SURE CHECK Ovulation Predictor Test to a substantially equivalent product (Self Care, Inc One-Step Ovulation Predictor Test) manufactured by Inverness. These data clearly demonstrate that the performance of the SURE CHECK Ovulation Predictor test is substantially equivalent to the Self Care, Inc. One-Step Ovulation Predictor.

Self Care, Inc. One-Step Ovulation Predictor vs. SURE CHECK Ovulation Predictor Test (Consumer User)

100 females tested the SURE CHECK Ovulation Predictor Test to determine their respective LH surges over a period of five consecutive days for one menstrual cycle. Each volunteer conducted the testing at home according to the package insert instructions. The urine samples obtained in the home testing each day were further tested with an FDA cleared ovulation predictor test (Self Care's One-Step Ovulation Predictor) to determine accuracy. The data obtained was recorded as NS for no surge, S for surge when observed.

RESULTS SUMMARY

Agreement	493
Discrepancies	7
Total	500

Accuracy = 98.6%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2001

Ms. Fran White
Chembio Diagnostic Systems, Inc.
c/o MDC Associates
163 Cabot Street
Beverly, MA 01915

Re: 510(k) NUMBER: K010244
Trade/Device Name: Sure Check Ovulation Predictor Test
Regulation Number: 862.1485
Regulatory Class: I, reserved
Product Code: CEP
Dated: March 6, 2001
Received: March 8, 2001

Dear Ms. White:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K010244
Device Name: SURE CHECK Ovulation Predictor Test

Indication for Use:

The SURE CHECK Ovulation Predictor Test is a qualitative, one-step, midstream assay for the detection of human Luteinizing Hormone (LH) in urine as an aid in conception by reliably predicting ovulation. The SURE CHECK Ovulation Predictor Test is intended for use by the lay consumer.

Jean Cooper

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510(k) Numbe... K010244

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** **Over The Counter Use** ✓
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**